

Theodore V. H. Mayer
 Vilia B. Hayes
 Robb W. Patryk
 HUGHES HUBBARD & REED LLP
 One Battery Park Plaza
 New York, NY 10004-1482
 (212) 837-6000
 hayes@hugheshubbard.com

Attorneys for Defendant Merck & Co., Inc.

UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF NEW YORK

----- X -----	:	
	:	
LYDIA AROCHO,	:	
	:	No.: 1:08-cv-4747
	:	
Plaintiff,	:	
	:	<u>ANSWER AND JURY DEMAND</u>
-against-	:	<u>OF DEFENDANT MERCK &</u>
	:	<u>CO., INC.</u>
MERCK & CO., INC.,	:	
	:	
Defendant.	:	
	:	
----- X -----		

Defendant Merck & Co., Inc. (“Merck”) answers Plaintiff’s Complaint (“Complaint”) herein as follows:

1. Upon information and belief, admits the allegations in paragraph 1 of the Complaint.
2. Denies each and every allegation contained in paragraph 2 of the Complaint, except admits that Merck is a New Jersey corporation, and that it is authorized to do business in the State of New York. Merck avers that its principle place of business is at One Merck Drive, Whitehouse Station, New Jersey.
3. Denies each and every allegation contained in paragraph 3 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medication

Vioxx® as safe and effective for certain indicated uses in a manner consistent with the relevant United States Food and Drug Administration (“FDA”)- approved prescribing information, and respectfully refers the Court to the relevant FDA-approved prescribing information for Vioxx for its indicated uses.

4. Denies each and every allegation contained in paragraph 4 of the Complaint.
5. Denies each and every allegation contained in paragraph 5 of the Complaint, except admits that Merck voluntarily withdrew Vioxx from the worldwide market on September 30, 2004, and that Merck scientists have participated in studies involving Vioxx and respectfully refers the Court to such studies for their actual conclusions and full context.
6. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 6 of the Complaint.
7. Denies each and every allegation contained in paragraph 7 of the Complaint.
8. Denies each and every allegation contained in paragraph 8, except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx, and states that the allegations as to implied warranty are legal conclusions as to which no responsive pleading is required.
9. Denies each and every allegation contained in paragraph 9 of the Complaint.
10. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 10 of the Complaint as to whether Vioxx was administered to Plaintiff. Denies each and every other allegation contained in said paragraph of the Complaint, except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.
11. Denies each and every allegation contained in paragraph 11 of the Complaint.

12. Denies each and every allegation contained in paragraph 12 of the Complaint.

RESPONSE TO "FIRST CAUSE OF ACTION"

13. With respect to the allegations contained in paragraph 13 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 12 of this Answer with the same force and effect as though set forth here in full.

14. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 14 of the Complaint, as to whether Vioxx was prescribed to Plaintiff. Denies each and every other allegation contained in said paragraph of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medicine Vioxx.

15. Denies each and every allegation contained in paragraph 15 of the Complaint.

16. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 16 of the Complaint.

17. Denies each and every allegation contained in paragraph 17 of the Complaint.

18. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 18 of the Complaint.

19. Denies each and every allegation contained in paragraph 19 of the Complaint.

20. Denies each and every allegation contained in paragraph 20 of the Complaint.

21. Denies each and every allegation contained in paragraph 21 of the Complaint.

RESPONSE TO "SECOND CAUSE OF ACTION"

22. With respect to the allegations contained in paragraph 22 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in

paragraphs 1 through 21 of this Answer with the same force and effect as though set forth here in full.

23. The allegations contained in paragraph 23 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

24. Denies each and every allegation contained in paragraph 24 of the Complaint.

25. Denies each and every allegation contained in paragraph 25 of the Complaint except admits that Merck manufactured, marketed and distributed the prescription medication Vioxx as safe and effective for certain indicated uses in a manner consistent with the relevant United States FDA-approved prescribing information, and respectfully refers the Court to the relevant FDA-approved prescribing information for Vioxx for its indicated uses.

26. Denies each and every allegation contained in paragraph 26 of the Complaint.

27. Denies each and every allegation contained in paragraph 27 of the Complaint.

RESPONSE TO "THIRD CAUSE OF ACTION"

28. With respect to the allegations contained in paragraph 28 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 27 of this Answer with the same force and effect as though set forth here in full.

29. The allegations contained in paragraph 29 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

30. Denies each and every allegation contained in paragraph 30 of the Complaint.

31. Denies each and every allegation contained in paragraph 31 of the Complaint.

32. Denies knowledge or information sufficient to form a belief as to the truth or falsity of the allegations contained in paragraph 32 of the Complaint.
33. Denies each and every allegation contained in paragraph 33 of the Complaint.
34. Denies each and every allegation contained in paragraph 34 of the Complaint.

RESPONSE TO "FOURTH CAUSE OF ACTION"

35. With respect to the allegations contained in paragraph 35 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 34 of this Answer with the same force and effect as though set forth here in full.

36. The allegations contained in paragraph 36 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

37. Denies each and every allegation contained in paragraph 37 of the Complaint.
38. Denies each and every allegation contained in paragraph 38 of the Complaint.
39. Denies each and every allegation contained in paragraph 39 of the Complaint.
40. Denies each and every allegation contained in paragraph 40 of the Complaint.
41. Denies each and every allegation contained in paragraph 41 of the Complaint.
42. Denies each and every allegation contained in paragraph 42 of the Complaint.
43. Denies each and every allegation contained in paragraph 43 of the Complaint.

RESPONSE TO "FIFTH CAUSE OF ACTION"

44. With respect to the allegations contained in paragraph 44 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in

paragraphs 1 through 43 of this Answer with the same force and effect as though set forth here in full.

45. Denies each and every allegation contained in paragraph 45 of the Complaint.
46. Denies each and every allegation contained in paragraph 46 of the Complaint.
47. Denies each and every allegation contained in paragraph 47 of the Complaint.
48. Denies each and every allegation contained in paragraph 48 of the Complaint.
49. Denies each and every allegation contained in paragraph 49 of the Complaint.
50. Denies each and every allegation contained in paragraph 50 of the Complaint.
51. Denies each and every allegation contained in paragraph 51 of the Complaint.
52. Denies each and every allegation contained in paragraph 52 of the Complaint.
53. The allegations contained in paragraph 53 of the Complaint are related to the Plaintiff's intake of Bextra, and are not directed towards Merck; therefore no responsive pleading is required. To the extent the allegations are directed towards Merck, Merck denies each and every allegation contained in said paragraph.

54. Denies each and every allegation contained in paragraph 54 of the Complaint.
55. Denies each and every allegation contained in paragraph 55 of the Complaint.
56. Denies each and every allegation contained in paragraph 56 of the Complaint.

RESPONSE TO "SIXTH CAUSE OF ACTION"

57. With respect to the allegations contained in paragraph 57 of the Complaint, Merck repeats and realleges each and every admission, denial, averment, and statement contained in paragraphs 1 through 56 of this Answer with the same force and effect as though set forth here in full.

58. The allegations contained in paragraph 58 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph except admits that certain laws and regulations govern the prescription drug approval process and respectfully refers the Court to the referenced laws for their actual language and full text.

59. The allegations contained in paragraph 59 of the Complaint are legal conclusions as to which no responsive pleading is required. Should a response be deemed required, Merck denies each and every allegation contained in said paragraph.

60. Denies each and every allegation contained in paragraph 60 of the Complaint.

61. Denies each and every allegation contained in paragraph 61 of the Complaint.

62. Denies each and every allegation contained in paragraph 62 of the Complaint.

63. Denies each and every allegation contained in paragraph 63 of the Complaint.

**AS FOR A FIRST
DEFENSE, MERCK ALLEGES:**

64. The claims of Plaintiff may be time-barred, in whole or in part, under applicable statutes of limitations or statutes of repose, or are otherwise untimely.

**AS FOR A SECOND
DEFENSE, MERCK ALLEGES:**

65. The Complaint fails to state a claim upon which relief can be granted.

**AS FOR A THIRD
DEFENSE, MERCK ALLEGES:**

66. The claims of Plaintiff may be barred, in whole or in part, from recovery because Plaintiff has made statements or taken actions that preclude her from asserting claims or constitute a waiver of her claims.

**AS FOR A FOURTH
DEFENSE, MERCK ALLEGES:**

67. The claims of Plaintiff may be barred, in whole or in part, from recovery because of the res judicata effect of prior judgments.

**AS FOR A FIFTH
DEFENSE, MERCK ALLEGES:**

68. Each and every claim asserted or raised in the Complaint is barred by the doctrines of estoppel, waiver or statutory and regulatory compliance.

**AS FOR A SIXTH
DEFENSE, MERCK ALLEGES:**

69. If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries or losses were caused in whole or in part through the operation of nature or other intervening cause or causes.

**AS FOR A SEVENTH
DEFENSE, MERCK ALLEGES:**

70. To the extent that Plaintiff asserts claims based on Merck's adherence to and compliance with applicable federal laws, regulations and rules, such claims are preempted by federal law under the Supremacy Clause of the United States Constitution.

**AS FOR AN EIGHTH
DEFENSE, MERCK ALLEGES:**

71. To the extent that Plaintiff asserts claims based upon an alleged failure by Merck to warn Plaintiff directly of alleged dangers associated with the use of Vioxx, such claims are barred under the learned intermediary doctrine because Merck has discharged its duty to warn in its warning to the prescribing physician.

**AS FOR A NINTH
DEFENSE, MERCK ALLEGES:**

72. If Plaintiff sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation manufactured or distributed by Merck or other manufacturer.

**AS FOR A TENTH
DEFENSE, MERCK ALLEGES:**

73. If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Merck and over whom Merck had no control and for whom Merck may not be held accountable.

**AS FOR AN ELEVENTH
DEFENSE, MERCK ALLEGES:**

74. If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were proximately caused by Plaintiff's misuse or abuse of Vioxx.

**AS FOR A TWELFTH
DEFENSE, MERCK ALLEGES:**

75. If Plaintiff sustained injuries or losses as alleged in the Complaint, such injuries or losses resulted from Plaintiff's pre-existing and unrelated medical, genetic and environmental conditions, diseases, or illnesses, subsequent medical conditions or natural courses of conditions for which this defendant is not responsible.

**AS FOR A THIRTEENTH
DEFENSE, MERCK ALLEGES:**

76. To the extent Plaintiff has settled or will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, Merck's liability, if any, should be reduced accordingly.

**AS FOR A FOURTEENTH
DEFENSE, MERCK ALLEGES:**

77. To the extent Plaintiff is seeking recovery for benefits entitled to be received or actually received from any other source for injuries alleged in the Complaint, such benefits are not recoverable in this action.

**AS FOR A FIFTEENTH
DEFENSE, MERCK ALLEGES:**

78. To the extent Plaintiff alleges fraud, such claims are barred by reason of Plaintiff's failure to allege the circumstances constituting fraud with particularity, as required by Sections 3013 and 3016(b) of the New York Civil Practice Law and Rules and Rule 9 (b) of the Federal Rules of Civil Procedure.

**AS FOR A SIXTEENTH
DEFENSE, MERCK ALLEGES:**

79. Plaintiff's claims are barred, in whole or in part, under the applicable state law because Vioxx was subject to and received pre-market approval by the Food and Drug Administration under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A SEVENTEENTH
DEFENSE, MERCK ALLEGES:**

80. Plaintiff's claims are barred in whole or in part by the First Amendment.

**AS FOR AN EIGHTEENTH
DEFENSE, MERCK ALLEGES:**

81. Plaintiff's claims are barred in whole or in part because the product at issue was made in accordance with the state of the art at the time it was manufactured.

**AS FOR A NINETEENTH
DEFENSE, MERCK ALLEGES:**

82. There is no practical or technically feasible alternative design that would have reduced the alleged risk without substantially impairing the reasonably anticipated and intended function of Vioxx.

**AS FOR A TWENTIETH
DEFENSE, MERCK ALLEGES:**

83. This case is more appropriately brought in a different venue.

**AS FOR A TWENTY-FIRST
DEFENSE, MERCK ALLEGES:**

84. The claims of Plaintiff may be barred, in whole or in part, from recovery because, in this or other courts, she has brought actions and has received judgments on parts of some or all claims asserted herein.

**AS FOR A TWENTY-SECOND
DEFENSE, MERCK ALLEGES:**

85. The claims of Plaintiff may be barred, in whole or in part, from recovery, on the ground that the claims asserted herein have been submitted to arbitration, and a binding decision has been rendered.

**AS FOR A TWENTY-THIRD
DEFENSE, MERCK ALLEGES:**

86. The claims of Plaintiff may be barred, in whole or in part, from recovery by release as to her claims.

**AS FOR A TWENTY-FOURTH
DEFENSE, MERCK ALLEGES:**

87. The claims of Plaintiff may be barred, in whole and in part, by the doctrine of laches.

**AS FOR A TWENTY-FIFTH
DEFENSE, MERCK ALLEGES:**

88. The claims of Plaintiff are barred, in whole or in part, by her failure to mitigate damages.

**AS FOR A TWENTY-SIXTH
DEFENSE, MERCK ALLEGES:**

89. To the extent there were any risks associated with the use of the product which is the subject matter of this action that Merck knew or should have known and which gave rise to a duty to warn, Merck at all times discharged such duty through appropriate and adequate warnings in accordance with federal and governing state laws.

**AS FOR A TWENTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

90. The claims of Plaintiff may be barred, in whole or in part, from recovery, due to spoliation of evidence.

**AS FOR A TWENTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

91. The claims of Plaintiff may be barred, in whole or in part, by the governing state laws.

**AS FOR A TWENTY-NINTH
DEFENSE, MERCK ALLEGES:**

92. Any conduct allegedly causing liability on the part of Merck is not a substantial cause or factor of any potential or actual injury or damage, if any.

**AS FOR A THIRTIETH
DEFENSE, MERCK ALLEGES:**

93. Plaintiff has not sustained any injury or damages compensable at law.

**AS FOR A THIRTY-FIRST
DEFENSE, MERCK ALLEGES:**

94. To the extent that Plaintiff seeks exemplary or punitive damages for the conduct which allegedly caused injuries asserted in the Complaint, such an award would also, if granted, violate Merck's state and federal constitutional rights.

**AS FOR A THIRTY-SECOND
DEFENSE, MERCK ALLEGES:**

95. To the extent that Plaintiff seeks exemplary or punitive damages for an alleged act or omission of Merck, no act or omission was malicious, willful, wanton, reckless, or grossly negligent and, therefore, any award of punitive damages is barred.

**AS FOR A THIRTY-THIRD
DEFENSE, MERCK ALLEGES:**

96. To the extent that Plaintiff seeks exemplary or punitive damages, such demand is barred because Vioxx and its labeling was subject to and received pre-market approval by the FDA under 52 Stat. 1040, 21 U.S.C. § 301.

**AS FOR A THIRTY-FOURTH
DEFENSE, MERCK ALLEGES:**

97. Plaintiff's claims are barred in whole or in part under comment k to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTY-FIFTH
DEFENSE, MERCK ALLEGES:**

98. Plaintiff's claims are barred in whole or in part because Merck provided adequate "directions or warnings" as to the use of Vioxx and any other drug or pharmaceutical preparation

Plaintiff is alleged to have taken within the meaning of comment j to Section 402A of the Restatement (Second) of Torts.

**AS FOR A THIRTY-SIXTH
DEFENSE, MERCK ALLEGES:**

99. Plaintiff's claims are barred under Section 4, et. seq., of the Restatement (Third) of Torts: Products Liability.

**AS FOR A THIRTY-SEVENTH
DEFENSE, MERCK ALLEGES:**

100. Plaintiff's claims are barred in whole or in part because Vioxx "provides net benefits for a class of patients" within the meaning of comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

**AS FOR A THIRTY-EIGHTH
DEFENSE, MERCK ALLEGES:**

101. Plaintiff's claims are barred by the doctrine of contributory negligence.

**AS FOR A THIRTY-NINTH
DEFENSE, MERCK ALLEGES:**

102. Any injuries, losses or damages suffered by Plaintiff were proximately caused, in whole or in part, by the failure of Plaintiff to exercise ordinary care and to follow the advice, information, warnings and/or instructions provided with the subject pharmaceutical product and therefore Plaintiff's recovery, if any, must be diminished by the proportion of the negligence of Plaintiff which proximately caused or contributed to the alleged injuries, losses or damages.

**AS FOR A FORTIETH
DEFENSE, MERCK ALLEGES:**

103. Plaintiff's claims are barred in whole or in part because the product at issue was not defective at the time that it left Merck's control.

**AS FOR A FORTY-FIRST
DEFENSE, MERCK ALLEGES:**

104. Plaintiff's claims for negligence per se are barred on the grounds that such claims are not cognizable against Merck in this action.

**AS FOR A FORTY-SECOND
DEFENSE, MERCK ALLEGES:**

105. Plaintiff's claims are barred, in whole or in part, because Plaintiff lacks capacity and/or standing to bring such claims.

Inasmuch as the Complaint does not describe the alleged underlying claims with sufficient particularity to enable Merck to determine all of its legal, contractual and equitable rights, Merck reserves the right to amend and supplement the averments of its answer to assert any and all pertinent liability defenses ascertained through further investigation and discovery of this action.

Merck will rely on all defenses that may become available during discovery or trial.

WHEREFORE, Merck respectfully demands judgment dismissing Plaintiff's Complaint with prejudice and awarding Merck its reasonable costs and disbursements, together with such and other and further relief that the Court may deem just and proper.

JURY DEMAND

Merck demands a trial by jury as to all issues so triable.

DATED: New York, New York
May 21, 2008

Respectfully submitted,

HUGHES HUBBARD & REED LLP

By: 

Theodore V. H. Mayer

Vilia B. Hayes

Robb W. Patryk

hayes@hugheshubbard.com

One Battery Park Plaza
New York, New York 10004-1482
(212) 837-6000

Attorneys for Defendant Merck & Co., Inc.

CERTIFICATE OF SERVICE

I hereby certify that on this the 22nd day of May, 2008, I caused a copy of the foregoing NOTICE OF REMOVAL OF DEFENDANT MERCK & CO., INC., and, ANSWER AND JURY DEMAND OF DEFENDANT MERCK & CO., INC., to be served via first-class mail, postage prepaid, on the following:

PODLOFSKY & ORANGE LLP

Ira C. Podlofsky, Esq.

98 Cutter Mill Road

Suite 299-North

Great Neck, New York, 11201

The above address has appeared on the prior papers in this action as the office address of the attorneys for the Plaintiff.

Deponent is over the age of 18 years and not a party to this action.

I further certify under penalty of perjury that under the laws of the United States of America the foregoing is true and correct.

Executed on May 22, 2008

Jennifer Alpern Hecht
Jennifer Alpern Hecht